

said MC8 has the characteristics of ATCC accession number 69674.--

REMARKS

Reconsideration of the application in view of the amendments above and remarks that follow is respectfully requested.

The present response is believed to fully meet all of the objections and rejections set forth in the Action (Paper No. 8). In addition, pursuant to the Examiner's request, Applicants have assessed the application for obvious errors and have not identified any at the present time.

Claims 1-29 have been canceled. New claims replace all the canceled claims except claim 21 that was withdrawn as to non-elected invention. The cancellation of all claims is without prejudice to Applicants' right to pursue the claimed subject matter in a timely-filed continuation application. The cancellation is expressly not to be construed as an abandonment of the subject matter or an acquiescence to any grounds for rejection that may be outstanding in this matter. Where appropriate, the Applicants have incorporated the Examiner's suggestions into the new claims. No additional claim fees are required. Support for incorporating the lambdoid bacteriophage matrix anchor having both head and tail polypeptides is provided at least on page 22, lines 12-21, page 36, lines 11-21, page 44, lines 17-35 continuing to page 45, lines 1-3, page 46, lines 4-14 and page 48, lines 17-33. Therefore, claims 30-56 are pending.

Applicants believe that no new matter has been introduced by the amendments made herein.

I. The Amendments

The specification has been amended on page 1 to incorporate priority information as requested by the Examiner and on page 133 to recite the respective ATCC designation numbers for MC8 and  $\gamma$ foo. Applicants also enclose copies of the ATCC deposit forms for each are also enclosed in the present response to support the

amendments.

Claims 1-10, 22-29 of Group I have now been canceled along with claim 21 of Group II. Group I claims are now replaced by claims 30-56 that are provided to more definitively define the scope of the claimed subject matter.

Applicants believe that no new matter is presented by the amendments to the claims as indicated above.

With regard to the comments, objections and rejections presented in the Action by the Examiner, Applicants' response continues below.

II. Drawings

The Examiner has noted that the application was filed with informal drawings. Formal drawings will be submitted when the application is allowed.

III. Claim Objections

The Examiner has objected to claims 8 and 11. Applicants have incorporated the Examiner's suggestions into the respective replacing claims 38 and 40.

IV. Rejection under 35 U.S.C. §112, First Paragraph

A. Claims 10 and 28-29

Claims 10 and 28-29 are rejected under 35 U.S.C. §112, first paragraph as the disclosure is allegedly enabling only for deposited biological materials.

The Examiner has requested that the specification be amended to indicate the respective ATCC Accession Numbers for MC8 and γfoo as described on page 133. Applicants have provided the requested amendments. In addition, copies of the ATCC deposit forms indicating the respective designations are provided in the present response to support the present amendments. The subject matter in claim 10,

γfoo, has now been canceled.

Therefore, Applicants respectfully request that the enablement rejections of original claims 10, 28-29 be withdrawn in view of the cancellation of subject matter and the incorporation of requested ATCC designations.

B. Claims 1-3, 6-8, 11-12, 15-20, and 22-29

Claims 1-3, 6-8, 11-12, 15-20, and 22-29 are rejected under 35 U.S.C. §112, first paragraph, as the disclosure is allegedly enabling for claims limited to vectors encoding or bacteriophage particles comprising fusions with lambdoid bacteriophage tail polypeptides that are pV.

The Examiner contends that the specification is only enabling for only the pV bacteriophage tail polypeptide and that successful incorporations of a foreign polypeptide into a fusion protein of the invention is somewhat unpredictable.

It is not necessary that an applicant test all the embodiments of his invention. *In re Angstadt*, 190 USPQ 214, 218 (C.C.P.A. 1976). What is necessary is that an applicant provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his claims. *Amgen v. Chugai*, 18 USPQ2d 1016, 1027 (Fed. Cir. 1990).

Applicants contend that the claims directed to tail proteins other than pV are sufficiently supported in the present disclosure enabling one of ordinary skill in the art to practice the invention. The present invention was the seminal work in the field demonstrating fusion protein expression on the surface of lambdoid bacteriophage in accordance with the disclosed methods. Moreover, the present inventors have also demonstrated that the present invention is not limited to the use of bacteriophage tail polypeptides but is extendable to bacteriophage head polypeptides as shown in the attached Exhibit I (Mikawa et al., *J. Mol. Biol.*, 262:21-30 (1996)). Furthermore, as demonstrated in Exhibit I (see page 27, column 2, first paragraph under Discussion), the present inventors have demonstrated that display of foreign proteins on the major head protein pD is accomplished at fusions at either the amino or carboxy terminus of

the pD.

Together, the head and tail bacteriophage polypeptides comprise the bacteriophage matrix anchor polypeptides of the present invention. Support of bacteriophages and vectors thereof in this context, including head and tail polypeptides, respectively including the preferred pD and pV matrix anchor polypeptides, as recited in the presently pending claims is provided at least on page 22, lines 12-21, page 36, lines 11-21, page 44, lines 17-35 continuing to page 45, lines 1-3, page 46, lines 4-14 and page 48, lines 17-33. Thus, in view of the present specification along with the support of data provided in Mikawa et al., Applicants contend that head protein fusions together with comparable fusions on tail proteins provide a reasonable and sufficient basis for the present claims directed to bacteriophage matrix anchor proteins and uses thereof in expression of fusion proteins on the surface of lambda bacteriophage. The inventors have thus demonstrated that they were the first parties to discover and reduce to practice a broad invention of surface display of proteins on bacteriophage matrix anchors. As such, Applicants contend that the present invention is enabled sufficiently to support a broad genus of lambdoid bacteriophage matrix anchor polypeptides for presenting foreign proteins on the surface of phage. In view of the support in the specification along with the documented evidence in Exhibit I, the invention is enabled sufficiently to support the alleged degree of unpredictability .

Therefore, in view of the foregoing, Applicants respectfully request that the rejections on this ground originally for claims 1-3, 6-8, 11-12, 15-20 and 22-29 be withdrawn and new claims 30-56 be passed on to allowance.

C. Claims 5 and 14

Claims 5 and 14 are rejected under 35 U.S.C. §112, first paragraph, as the disclosure is allegedly enabling only for claims limited to pV.

The Examiner contends that the phrase "conservative substitutions thereof" is not taught nor disclosed in the specification to the extent that conservative

substitutions of the given pV sequence result in a fusion protein having the same properties.

In view of the cancellation of claims 5 and 14 and no replacement claims, the rejection is rendered moot. Applicants thus respectfully request that the rejection be withdrawn.

V. Rejection under 35 U.S.C. §112, Second Paragraph

A. Claims 5, 7, 9-20, 22-26, and 29

Claims 5 and 14 are rejected for reciting "and conservative substitutions thereof". The claims have now been canceled and the subject matter is not present in the replacement claims 30-56. Thus, Applicants request that the rejection be withdrawn as it is no longer applicable.

Claim 7 is rejected for reciting "from about 10 to about 100". The Applicants have removed the word "about" from the claim, thereby eliminating the alleged indefiniteness. Thus, Applicants request that the rejection be withdrawn as it is no longer applicable.

Claim 9 is rejected for reciting the allegedly indefinite phrase "has a nucleotide sequence shown in SEQ ID NO 5". Applicants have amended the claim in accordance with the Examiner's suggestion to indicate the entire nucleotide sequence of SEQ ID NO 5. Thus, Applicants request that the rejection be withdrawn as it is no longer applicable.

Claim 10 is rejected for reciting "functionally similar thereto". Since the claim has been canceled and is not present in claims 30-56, the rejection is no longer relevant.

Claims 11-20 are rejected for reciting "consisting essentially of". Applicants have amended claim 40, replacing claim 11, to read "consists of". Thus, Applicants request that the rejection be withdrawn as it is no longer applicable.

Claim 13 is rejected for reciting "The lambdoid bacteriophage vector" that lacks antecedent basis. Since the claim has been canceled and is not present in claim

13, the rejection is no longer relevant.

Claim 16 is rejected for reciting "capable of forming". Applicants have amended replacement claim 46 with the Examiner's suggestions. Thus, Applicants request that the rejection be withdrawn as it is no longer applicable.

Claim 17 is rejected for not definitively reciting the multimeric protein of the invention. Applicants have amended claim 47, replacing claim 17, to more definitively define the invention. Support for the amendments are at least provided at page 14, lines 20-28. In view of the present amendments, Applicants respectfully request that the rejection be withdrawn.

Claims 22 and 23 are rejected for not clearly reciting a library containing different members. Claims 22 and 23 have been canceled and replaced by claim 51 in which the suggested library has been incorporated. In view of the present amendments, Applicants respectfully request that the rejection be withdrawn.

Claim 24 is rejected for being dependent on a non-elected claim, claim 21. Claim 24 has been replaced with claim 52 in which the limitations of claim 21 have been incorporated. In view of the present amendments, Applicants respectfully request that the rejection be withdrawn.

Claims 25-26 are rejected for reciting "able to bind". Applicants have incorporated the Examiner's suggestions into pending claim 52. In view of the present amendments, Applicants respectfully request that the rejection be withdrawn.

Claim 29 is rejected for lacking the ATCC accession number. Pending claim 55 now recites the requested information. In view of the present amendments, Applicants respectfully request that the rejection be withdrawn.

Thus, in view of the foregoing discussions and amendments, Applicants contend that all the indefinite rejections have been overcome and respectfully request that the rejections be withdrawn.

#### VI. Double Patenting

Claims 4, 5, 13 and 14 are rejected under 35 U.S.C. §101 as claiming

the same invention as that of claims 1, 3, 9 and 10 of prior U.S. Patent No. 5,627,024. Claims 1-3, 6-12, 14-20 and 22-29 are also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,627,024.

Claims 4, 5, 13 and 14 have been canceled and not replaced with the presently pending claims 30-56. Therefore, the rejection of double patenting under 35 U.S.C. §101 is rendered moot. However, upon an indication of allowance of the pending claims, Applicants will file a terminal disclaimer to overcome the obviousness-type double patenting rejection of claims 1-3, 6-12, 14-20 and 22-29, now replaced by claims 30-56.

#### VII. Priority

The Examiner has indicated that application was filed as a divisional although Applicant indicated that the application was to be treated as a §1.60 continuation. Applicant has accordingly amended the specification to indicate the relationship with the priority application. In addition, Applicant does not believe that any amendment or replacement of the declaration is required. However, to the extent that any papers need to be replaced, Applicant requests that the Examiner provide the relevant instructions.

#### VIII. Summary

Applicants believe they have fully responded in the foregoing amendments and remarks to each issue and grounds for rejection and objection raised by the Examiner. Applicants submit that patentable subject matter exists with regard to the pending claims and therefore respectfully request favorable action. The application is now believed to be in proper condition for allowance and early notification of allowance is earnestly solicited. The Examiner is invited to telephone

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13

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the undersigned if it would be deemed helpful to advance the application.

Respectfully submitted,

6/23/98  
DATE

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record  
☐ [ ] Filed under §1.34a





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## BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

### INTERNATIONAL FORM

#### RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

The Scripps Research Institute  
Attention: Michael T. White  
10666 N. Torrey Pines Road  
La Jolla, CA 92037

AUG 31 1994

Deposited on Behalf of: The Scripps Research Institute (SCR1559P/TSRI432.0)

Identification Reference by Depositor:

ATCC Designation

Bacteriophage lambda DNA, lambda foo

75850

The deposit was accompanied by: ☐ a scientific description ☐ a proposed taxonomic description indicated above.

The deposit was received August 4, 1994 by this International Depository Authority and has been accepted.

#### AT YOUR REQUEST:

☒ We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested August 18, 1994. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Date: August 22, 1994

Harold D. Hatt, Acting Head, ATCC Patent Depository

cc: Douglas A. Bingham, Esq.

Form BP4/9



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## BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

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AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

The Scripps Research Institute  
Attention: Michael T. White  
10666 North Torrey Pines Road  
Office of Technology Transfer, TPC 9  
La Jolla, CA 92037

AUG 16 1994

Deposited on Behalf of: The Scripps Research Institute (SCR1559P/TSRI432.0)

Identification Reference by Depositor:

ATCC Designation

Escherichia coli, MC8

69674

The deposit was accompanied by: \_\_\_ a scientific description X a proposed taxonomic description indicated above.

The deposit was received August 4, 1994 by this International Depository Authority and has been accepted.

#### AT YOUR REQUEST:

X We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested August 9, 1994. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Harold D. Hatt Date: August 10, 1994  
Harold D. Hatt, Acting Head, ATCC Patent Depository

cc: Douglas A. Bingham, Esq. ✓

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